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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,122	04/14/2004	Richard Rox Anderson	022727-0110	3121

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EXAMINER

KARPINSKI, LUKE E

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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07/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/709,122	Applicant(s) ANDERSON ET AL.	
	Examiner LUKE E. KARPINSKI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-22, 44 and 47 is/are allowed.
- 6) ☒ Claim(s) 1, 23-34, 45, 46 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/09/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendments, arguments, and remarks files 4/03/2009 is acknowledged.

Claims

Claims 1-34 and 44-50 are pending.

Claims 35-43 are canceled.

Claims 48-50 are new.

Claims 24-27, 29-33, 45, and 46 are amended.

Claims 1-34 and 44-50 are under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,050,990 to Tankovich et al. in view of US Patent No. 5,709,654 to Klatz et al. and US Patent No. 5,114,973 to Hess et al.

Applicant Claims

Applicant claims a method for protecting epithelial tissue during hair removal utilizing photodynamic therapy induced using a pre-photosensitizing agent. The method comprising: administering said pre-photosensitizing agent, preventing the metabolism of the pre-photosensitizing agent into a photosensitizing agent while still allowing the metabolism to occur at the desired treatment site, and irradiating the treatment site wherein the tissue surrounding the treatment site is substantially unaffected.

Applicant further claims a chemical inhibitor utilized to prevent said metabolism, said inhibitor being applied to epithelial tissue

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Tankovich et al. teach topical application of aminolevulinic (ALA) acid for use in photodynamic therapy (col. 39, lines 58 to col. 40, line 17) as pertaining to claims 1, 23-34, 45, 46, and 48-50.

Klatz et al. teach that free radicals damage tissue (entire disclosure).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Neither Tankovich et al. et al, nor Klatz et al. teach the application of an inhibitor to prevent metabolism of a pre-photosensitizing agent. This deficiency is cured by Hess et al. Hess et al. teach succinylacetone being an inhibitor of the second enzyme of the heme biosynthetic pathway, which is aminolevulinic acid (col. 1).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Regarding claims 1 and 23, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply a pre-photosensitizing inhibitor to non-treatment target sites in order to prevent metabolism of a photosensitizing agent in order to protect epithelial tissue during photo dynamic therapy (PDT), as taught by a combination of Tankovich et al., Klatz et al., and Hess et al. in order to produce the invention of instant claims 1 and 23.

One of ordinary skill in the art would have been motivated to do this because Tankovich et al. teach application of a pre-photosensitizing agent (ALA) and that sunlight will activate said agent and cause damage to the tissue which it is applied, Klatz et al. teach that free radicals damage tissue, and Hess et al. teach that succinylacetone inhibits the metabolism of ALA Therefore it would have been obvious

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to apply succinylacetone to areas which damage to said tissue is not desired in order to prevent said metabolism of ALA to a photoactive compound.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 4/03/2009 have been fully considered but they are not persuasive.

Applicant argues that none of the references cited teach application of a chemical inhibitor in order to prevent metabolism of a pre-photosensitizing agent in a non-targeted site while allowing metabolism to occur in a targeted site.

This argument is not found persuasive because utilization of ALA in PDT is well known, as is the fact that succinylacetone as an inhibitor of the metabolism of ALA. It is also well known in the art that ALA is topically administered to areas of treatment, with the knowledge that said ALA will metabolize into a photoactive agent. With the knowledge that said metabolism could be inhibited, it would be obvious to one of ordinary skill in the art to administer said inhibitor to the non-treatment sites adjoining the treatment site in order to protect the non-targeted tissue from any damage. As one of ordinary skill in the art would be a medical doctor, and doctors have taken an oath to

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do no harm, preventing damage to non-targeted, healthy tissue, would be on the forefront of their mind.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 24-34, 45, 46, and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,050,990 to Tankovich et al. in view of US Patent 5,114,973 to Hess et al. and US Patent 5,955,490 to Kennedy et al.

Applicant Claims

Applicant claims a method for protecting tissue during PDT comprising administering a pre-photosensitizing agent to epithelial and a targeted tissue, preventing metabolism of said agent in the epithelial tissue while allowing metabolism of said agent in said targeted tissue, irradiating said tissues within a temperature range to activate said agent and that the temperature of said epithelial tissue is less than that of said target tissue.

Applicant also claims the application of a chemical inhibitor in order to prevent said metabolism, percentages of said inhibitor, specific inhibitors, application times, said inhibitor in a cream, said cream comprising said pre-photosensitizing agent, application of said agents at different times, cooling said epithelial tissue prior to irradiation, concentrations of said pre-photosensitizing agents, and temperatures of said target site.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Tankovich et al. teach application of ALA to target and destroy hair follicle cells (abstract and cols. 37-40, no. 8), as pertaining to claims 48 and 50.

Tankovich et al. also teach about 2% photochemical (ALA) (col. 38 3rd paragraph) as pertaining to claim 34, and that said compositions are applied topically with massage (col. 38 4th paragraph) as pertaining to claims 26 and 46.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Tankovich et al. do not teach utilization of a chemical inhibitor to prevent metabolism of said ALA as pertaining to claims 23, 25, 31-34, 48 and 50. This deficiency in Tankovich et al. is cured by Hess et al. Hess et al. teach that succinylacetone as a chemical inhibitor to the metabolism of ALA (col. 1, last paragraph)

Further, Tankovich et al. do not teach the application of ALA and cooling the epithelial tissue before irradiating as claimed in claim 30. However Tankovich et al. do teach cooling the skin to prevent damage to the tissue.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

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Regarding claims 48 and 50, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply a chemical inhibitor to inhibit the metabolism of ALA in order to produce the invention of instant claims 48 and 50.

One of ordinary skill in the art would have been motivated to do this because the utilization of ALA in PDT is well known, as is the fact that ALA metabolizes into a photosensitive agent and causes damage to surrounding tissue when irradiated. It was also known at the time of the invention that succinylacetone inhibits the metabolism of ALA. Therefore it would have been obvious to apply the succinylacetone of Hess et al., to non-targeted tissue to inhibit the metabolism of ALA and prevent damage to untargeted tissue.

Regarding claim 30, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to cool the epithelial tissue prior to irradiation in order to practice the invention of claim 30.

One of ordinary skill in the art would have been motivated to do this because Tankovich et al. tech that cooling the skin can reduce tissue damage. Although these steps are from 2 separate methods of Tankovich et al. it is the examiners belief that one of skill would be well aware that method 8 could be modified to utilize a laser in a medical setting rather than use sunlight in an at-home setting, with this modification it would be obvious to cool the skin as in method 22 to prevent further tissue damage.

Regarding claims 24 and 45 and the percentage of chemical inhibitor utilized, it would be routine experimentation to determine how much inhibitor is required to prevent metabolism to the extent desired.

Regarding claims 26 and 46, it would be obvious to alter the application times of said compositions in order to ensure the desired coverage and the application of the desired amount of compound. It would also be obvious to massage said compositions into the skin.

Regarding claim 27, it would have been obvious to supply the compositions of Tankovich et al. in any number of medically acceptable topical application forms, including as a cream.

Regarding claims 28 and 29, it would have been obvious to apply said inhibitor at the same or different times than said ALA due to the fact that said inhibitor cannot inhibit the metabolism of ALA if it is not present to do so before said metabolism occurs. Further it is obvious to have 2 different components in the same composition or different.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claims 2-22, 44, and 47 are allowed.

The following is an examiner's statement of reasons for allowance: Claims 2-22, 44, and 47 are drawn to a method for protecting epithelial tissue during PDT comprising administering a pre-photosensitizing agent to epithelial tissue and targeted tissue and preventing the metabolism of said pre-photosensitizing agent in said epithelial tissue while allowing metabolism to occur in said targeted tissue by creating a temperature gradient and irradiating said targeted site.

The prior art does not anticipate, teach, or suggest either alone or in combination methods of applying a pre-photosensitizing agent and preventing the metabolism of said agent through temperature control. The methods and principles of claims 2-22, 44, and 47 have been thoroughly searched and no other prior art has been found which would render said methods anticipated or obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 35-43 are canceled.

Claims 1, 23-34, 45, 46, and 48-50 are rejected.

Claims 2-22, 44, and 47 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK
/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616

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